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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,651	03/01/2004	James F. Zucherman	SFMT-01056USE	9758

23910 7590 03/20/2007  
FLIESLER MEYER LLP  
650 CALIFORNIA STREET  
14TH FLOOR  
SAN FRANCISCO, CA 94108

EXAMINER
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CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/20/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/790,651

Applicant(s)

ZUCHERMAN ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_ 01/12/07, 02/14/05
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

## **DETAILED ACTION**

### ***Specification***

Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:

- (1) if a machine or apparatus, its organization and operation;
- (2) if an article, its method of making;
- (3) if a chemical compound, its identity and use;
- (4) if a mixture, its ingredients;
- (5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the limitation "at least one of the second lateral sides" in lines 3-4. There is insufficient antecedent basis for this limitation in the claim. It appears that there is only one second lateral side.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-47, as best understood by the examiner, are rejected under 35 U.S.C. 102(e) as being anticipated by Brumfield et al. (US Pat. 5,562,662).

Brumfield et al. disclose a method for lateral insertion of an interspinous process implant comprising the steps of: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); inserting the interspinous process implant (Fig. 2, ref. 20) between the spinous processes from a first lateral side of the spinous processes (Fig. 2)(column 9, lines 55-57, since in passing through the bores in ref. 29, it must pass from one side to the other side) and causing the interspinous process implant inserted by the inserting step to deploy adjacent a second lateral side of at least one of the spinous processes (column 10, lines 3-14). The definition of "deploy" according to the Merriam-Webster Online Dictionary is "to spread out, utilize, or arrange for a deliberate purpose." The device of Brumfield et al. can be considered to

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be deployed, since it is being utilized and arranged for a deliberate purpose (i.e. to draw the rods 21 together, column 10, lines 10-14) and is adjacent to the spinal processes on both sides (Fig. 2). The method further comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The insertion step causes a wing (Fig. 3C, ref. 27) to be positioned adjacent to the first lateral side of at least one of the spinous processes (Fig. 2, since refs. 27 are on both lateral sides). The causing step causes a wing (Fig. 3C, ref. 27) to be deployed adjacent to the second lateral side (Fig. 2, since refs. 27 are on both lateral sides) of at least one of the spinous processes. The insertion step causes a first wing (Fig. 3C, ref. 27) to be positioned adjacent to the first lateral side of at least one of the spinous processes (Fig. 2, since refs. 27 are on both lateral sides) and the causing step causes a second wing (Fig. 3C, ref. 27) to be deployed adjacent to at least one of the second lateral sides of the spinous processes (Fig. 2, since refs. 27 are on both lateral sides).

Brumfield et al. disclose a method for lateral insertion of an interspinous process implant comprising the steps of accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); inserting the interspinous process

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implant (Fig. 2, ref. 20) between the spinous processes from a first lateral side of the spinous processes (Fig. 2)(column 9, lines 55-57, since in passing through the bores in ref. 29, it must pass from one side to the other side); urging the interspinous process implant through to the second lateral side of the spinous processes (Fig. 2)[column 9, lines 55-57, since in passing through the bores in ref. 29, it must pass from one side to the other side, and must be pushed (e.g. urged) into position]; and causing the interspinous process implant inserted by the inserting step to deploy adjacent a second lateral side of at least one of the spinous processes (column 10, lines 3-14). The definition of "deploy" according to the Merriam-Webster Online Dictionary is "to spread out, utilize, or arrange for a deliberate purpose." The device of Brumfield et al. can be considered to be deployed, since it is being utilized and arranged for a deliberate purpose (i.e. to draw the rods 21 together, column 10, lines 10-14) and is adjacent to the spinal processes on both sides (Fig. 2).

Brumfield et al. disclose a method for lateral insertion of an interspinous process implant comprising the steps of: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); inserting the interspinous process implant (Fig. 2, ref. 20) between the spinous processes from a first lateral side of the spinous processes (Fig. 2)(column 9, lines 55-57, since in passing through the bores in ref. 29, it must pass from one side to the other side); and positioning the interspinous process implant inserted in the inserting step (column 10, lines 10-14), where the interspinous process implant extends from a second lateral side (Fig. 2, since it extends along both lateral sides). The method further comprises a step of distracting the spinous

processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The insertion step places an interspinous process implant member (Fig. 2, ref. 38) adjacent to the first lateral side of at least one of the spinous processes. The interspinous process implant member is selected from a wing, an arm, a leg (Fig. 2, ref. 38), and a hook. The positioning step places an interspinous process implant member (Fig. 2, ref. 38) adjacent to the second lateral side of at least one of the spinous processes (Fig. 2). The interspinous process implant member is selected from a wing, an arm, a leg (Fig. 2, ref. 38), and a hook.

Brumfield et al. disclose a method for the lateral insertion of an interspinous process implant, where the steps of inserting the interspinous process implant comprise: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); inserting the interspinous process implant (Fig. 2, ref. 20) laterally between the spinous processes (Fig. 2, near ref. 38), said interspinous process implant comprising a body (Fig. 2, refs. 21 and 38) having a deployable interspinous process implant member (Fig. 2, ref. 38 and ref. 21 on one side of processes); and deploying the implant member (column 10, lines 3-14), where the implant member extends from a second lateral side of the spinous processes. The method further

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comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The insertion step places an interspinous process implant member (Fig. 2, ref. 38 and ref. 21 on one side of processes) adjacent to the first lateral side of at least one of the spinous processes (Fig. 2). The interspinous process implant member is selected from a wing, an arm, a leg (Fig. 2, ref. 38 and ref. 21 on one side of processes), and a hook. The deploying step places an interspinous process implant member (Fig. 2, ref. 38 and ref. 21 on one side of processes) adjacent to the second lateral side of at least one of the spinous processes (Fig. 2). The interspinous process implant member is selected from a wing, an arm, a leg (Fig. 2, ref. 38 and ref. 21 on one side of processes), and a hook. The step of inserting further comprises using at least one tool (column 9, lines 65-67, i.e. driving tool) for lateral insertion of the interspinous process implant (Fig. 2).

Brumfield et al. disclose a method for the lateral insertion of an interspinous process implant, where the steps of inserting the interspinous process implant comprise: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); and inserting the interspinous process implant (Fig. 2, ref. 20)



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laterally between said spinous processes (Fig. 2, near ref. 38), said interspinous process implant comprising: a body (Fig. 2, refs. 21 and 38) adapted to be placed between spinous processes (Fig. 2, ref. 38), where the body has a proximal end (Fig. 2, end near ref. 38) and a distal end (Fig. 2, end opposite proximal end); and a distraction guide (Fig. 2, ref. 25) extending from the distal end of the body. The method further comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The step of inserting further comprises using at least one tool (column 9, lines 65-67, i.e. driving tool) for lateral insertion of the interspinous process implant (Fig. 2). The interspinous process implant further comprises at least one wing (Fig. 2, any of refs. 25).

Brumfield et al. disclose a method for the lateral insertion of an interspinous process implant, where the steps of inserting the interspinous process implant comprise: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); and inserting the interspinous process implant laterally between said spinous processes (Fig. 2, portion near ref. 38), said interspinous process implant comprising: a central body (Fig. 2, refs. 21 and 38) with a proximal end (Fig. 2, end near

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ref. 38) and a distal end (Fig. 2, end opposite proximal end) , said central body having a longitudinal axis (along the length of the body); a sleeve (Fig. 12, refs. 115, 137 and 135) associated with the central body (Fig. 12), where the sleeve is adapted to be placed between spinous processes; and a distraction guide (Fig. 2, ref. 25) extending from the distal end of the central body (Fig. 2). The method further comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The step of inserting further comprises using at least one tool (column 9, lines 65-67, i.e. driving tool) for lateral insertion of the interspinous process implant (Fig. 2). The interspinous process implant further comprises at least one wing (Fig. 2, any of refs. 25).

Brumfield et al. disclose a method for the lateral insertion of an interspinous process implant, where the steps of inserting the interspinous process implant comprise: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); and inserting the interspinous process implant (Fig. 2, ref. 20) laterally between said spinous processes (Fig. 2, portion near ref. 38), said interspinous process implant comprising: a central body (Fig. 2, refs. 21 and 38) with a proximal end (Fig. 2, end near ref. 38) and a distal end (Fig. 2, end opposite proximal end), said

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central body having a longitudinal axis (the axis along the length of the device); a wing (Fig. 2, ref. 25) located at the proximal end of the central body; a sleeve (Fig. 12, ref. 115) associated with the central body, where the sleeve is adapted to be placed between spinous processes; and a distraction guide (Fig. 2, ref. 25) extending from the distal end of the central body. The method further comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. The step of inserting further comprises using at least one tool (column 9, lines 65-67, i.e. driving tool) for lateral insertion of the interspinous process implant (Fig. 2). The interspinous process implant further comprises a second wing (Fig. 12, ref. 25) located near the distal end of the central body.

Brumfield et al. disclose a method for the lateral insertion of an interspinous process implant, where the steps of inserting the interspinous process implant comprise: accessing the spinous processes laterally (Fig. 2)(column 5, lines 51-55) (column 9, lines 50-53); and inserting the interspinous process implant laterally between said spinous processes (Fig. 2, portion near ref. 38), said interspinous process implant comprising: a body (Fig. 2, refs. 21 and 38) adapted to be placed between spinous

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processes, the body having a proximal end (Fig. 2, end closer to ref. 38) defining a first saddle (Fig. 2, ref. 28, top right), and a distal end (Fig. 2, end further from ref. 38) defining a second saddle (Fig. 2, ref. 28, top left); and the first saddle and the second saddle are adapted to receive adjacent spinous processes. The method further comprises a step of distracting the spinous processes apart, since, as seen in Fig. 12, ref. 137 is placed in between ref. 142 and V1, which would necessarily distract the components (e.g. the spinous processes on adjacent vertebrae) that are adjacent to ref. 137, and the distracting step and the inserting step are done in any order. The method further comprises a step of distracting the spinous processes apart, where the distracting step and the inserting step are done simultaneously, since the step of inserting can be considered to include inserting refs. 137 into position as shown in Fig. 12. After the insertion step the method further comprises a step of positioning the interspinous process implant (column 10, lines 10-14) between the spinous processes (Fig. 2, near ref. 38). The interspinous process implant further comprises positioning means (Fig. 2, refs. 25), where the positioning means retain the interspinous process implant between the spinous processes to limit extension and allow flexion. The positioning means is a tether (Fig. 2, refs. 25). The positioning means is a pin (Fig. 2, refs. 25). The positioning means is at least one arm extending from the proximal end and distal end of the interspinous process implant (Fig. 2, refs. 25). The positioning means further comprises a tether (Fig. 2, refs. 25). The step of inserting further comprises using at least one tool (column 9, lines 65-67, i.e. driving tool) for lateral insertion of the interspinous process implant.

**Conclusion**

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT  
SUPERVISORY PATENT EXAMINER